

AMENDMENT TO THE CLAIMS

Claims 1, 4-8, 11, 14, 19-21, 24, 28-30 and 35-37 are currently pending. Claims 2-3, 9-10, 12-13, 15-18, 22-23, 25-27, and 31-34 have been canceled. Claims 1, 14 and 24 are currently amended. Claims 38-40 are new. This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1. (Currently Amended) A method for identifying a patient as a candidate for additional colorectal cancer testing, comprising the steps of:

determining a quantitative amount of genome equivalents of patient genomic DNA in a stool sample comprising shed cells and shed cellular debris, wherein the quantitative amount of genome equivalents is determined by measuring an amount of amplified nucleic acid fragments amplified from shed cells and shed cellular debris, said fragments having length of 200 bp or less; and

identifying the patient as a candidate for additional cancer testing if the amount of genome equivalents is above a predetermined threshold amount of genome equivalents, wherein the predetermined threshold amount of genome equivalents comprises at least 10 genome equivalents.

2.-3. (Canceled)

4. (Previously Presented) The method of claim 1, further comprising the step of performing an additional assay on a stool sample from the patient if the patient is identified as a candidate for additional cancer testing.

5. (Previously Presented) The method of claim 4, wherein the assay is selected from the group consisting of a DNA integrity assay, mutation detection, enumerated loss of heterozygosity (LOH), expression assays, and fluorescent in situ hybridization (FISH).

6. (Original) The method of claim 4, wherein the assay detects mutations at a genetic locus selected from the group consisting of p53, ras, APC, DCC, and BAT-26.

7. (Previously Presented) The method of claim 1, further comprising the step of performing a diagnostic examination on the patient if the patient is identified as a candidate for additional cancer testing.

8. (Previously Presented) The method of claim 7, wherein the step of performing a diagnostic examination is selected from the group consisting of a colonoscopy, a sigmoidoscopy, a fecal occult blood testing and an upper gastrointestinal evaluation.

9.-10. (Canceled)

11. (Previously Presented) The method of claim 1, wherein the cancer is colorectal cancer or pre-cancer.

12.-13. (Canceled)

14. (Currently Amended) A method for screening a patient for the presence of abnormal proliferating colorectal cancer cells, comprising the steps of:

determining a quantitative amount of genome equivalents of patient genomic DNA in a stool sample comprising shed cells and shed cellular debris, wherein the quantitative amount of genome equivalents is determined by measuring an amount of amplified nucleic acid fragments amplified from shed cells and shed cellular debris, said fragments having length of 200 bp or less;

identifying a positive screen as a sample in which the amount of genome equivalents is above a predetermined threshold amount of genome equivalents, wherein the predetermined threshold amount of genome equivalents comprises at least 10 genome equivalents; and

performing at least one additional assay to detect at least one marker indicative of colorectal cancer or precancer on a stool sample from the patient identified as a positive screen to

determine if the patient has abnormal proliferating colorectal cancer cells, wherein the at least one additional assay is selected from the group consisting of a DNA integrity assay, mutation detection, enumerated loss of heterozygosity (LOH), expression assays, and fluorescent in situ hybridization (FISH), and wherein a positive result of said at least one additional assay indicates the patient has abnormal proliferating colorectal cancer cells.

15.-18. (Canceled)

19. (Previously Presented) The method of claim 14, wherein the at least one additional assay comprises detection of mutations at a genetic locus selected from the group consisting of p53, ras, APC, DCC, and BAT-26.

20. (Original) The method of claim 14, further comprising the step of performing a diagnostic examination on the patient if a positive screen is identified in the identifying step.

21. (Original) The method of claim 20, wherein the step of performing a diagnostic examination is selected from the group consisting of a colonoscopy, a sigmoidoscopy, a fecal occult blood testing and an upper gastrointestinal evaluation.

22.-23. (Canceled)

24. (Currently Amended) A method for diagnosing colorectal cancer or precancer in a patient, comprising the steps of:

determining a quantitative amount of genome equivalents of patient genomic DNA in a stool sample comprising shed cells and shed cellular debris, wherein the quantitative amount of genome equivalents is determined by measuring an amount of amplified nucleic acid fragments amplified from shed cells and shed cellular debris, said fragments having length of 200 bp or less; and

if the amount of genome equivalents is above a predetermined threshold amount of genome equivalents, wherein the predetermined threshold amount of genome equivalents comprises at least 10 genome equivalents.

performing at least one additional assay to detect at least one marker indicative of colorectal cancer or precancer to determine if the patient has colorectal cancer or precancer, wherein the at least one additional assay is selected from the group consisting of a DNA integrity assay, mutation detection, enumerated loss of heterozygosity (LOH), expression assays, and fluorescent in situ hybridization (FISH); and wherein a positive result of said at least one additional assay indicates that the patient has colorectal cancer or precancer.

25.-27. (Canceled)

28. (Previously Presented) The method of claim 24, wherein the at least one additional assay comprises detection of mutations at a genetic locus selected from the group consisting of p53, ras, APC, DCC, and BAT-26.

29. (Original) The method of claim 24, wherein the method further comprises performing a diagnostic examination of the patient.

30. (Original) The method of claim 29, wherein the diagnostic examination is selected from the group consisting of a colonoscopy, a sigmoidoscopy, a fecal occult blood testing and an upper gastrointestinal evaluation.

31.-34. (Canceled)

35. (Previously Presented) The method of claim 1, wherein the amount of amplified nucleic acid fragments is determined by quantitative PCR.

36. (Previously Presented) The method of claim 14, wherein the amount of amplified nucleic acid fragments is determined by quantitative PCR.

37. (Previously Presented) The method of claim 24, wherein the amount of amplified nucleic acid fragments is determined by quantitative PCR.

38. (New) The method of claim 1 wherein the predetermined threshold of genome equivalents comprises at least 500 genome equivalents.

39. (New) The method of claim 1 wherein the predetermined threshold of genome equivalents comprises at least 650 genome equivalents.

40. (New) The method of claim 1 wherein the predetermined threshold of genome equivalents comprises at least 1000 genome equivalents.